

## REMARKS

### **The Amendments**

The claims have been amended for clarity and do not constitute narrowing amendments. No new matter is added by the new claims. Applicants respectfully request entry of this amendment and consideration of the below remarks. In light of these amendments and remarks, applicants respectfully request reconsideration of this application.

### **Rejection of Claim 15, 16, and 24 Under 35 U.S.C. §112, second paragraph**

Claims 15, 16, and 24 stand rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. Applicants respectfully traverse the rejection.

The Office asserts that claims 15, 16, and 24 are unclear because claim 10(d) states that the “nucleic acid enzyme is added in the first reaction vessel.” However, claim 10(d) does not state the nucleic acid amplification enzyme is added to the first reaction vessel. Instead, the claim recites that the product from the first reaction vessel is contacted with the enzyme. The claim does not require that the amplification take place in the first reaction vessel. Dependant claims 15, 16, and 24 specify where the product from the first reaction vessel is contacted with the enzyme. One of skill in the art, given the specification, would understand what is claimed. The claims are clear and Applicants respectfully request withdrawal of the rejection.

### **Rejection of Claims 10, 11, 14-16, 21-25, 27, and 30-35 Under 35 U.S.C. §102(e)**

Claims 10, 11, 14-16, 21-25, 27, and 30-35 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 5,856,174 (“the ‘174 patent”). Applicants respectfully traverse the rejection.

Anticipation under 35 U.S.C. § 102 requires the presence in a single prior art disclosure of each and every element of a claimed invention. *Lewmar Marine Inc. v. Barient Inc.*, 3 USPQ2d 1766, 1767 (Fed. Cir. 1987).

The instant invention provides a first reaction vessel wherein a hybridization product is formed between a first nucleic acid and at least one oligonucleotide primer and a second reaction vessel wherein the first nucleic acid is amplified. This is advantageous because it keeps the heat stable sample/amplification reagents (specific primers and nucleotides) separated from the heat labile enzymatic components (e.g., RNA reverse

transcriptase, RNA polymerase, RNaseH). *See, e.g.*, specification, page 18, lines 24-26. The heat labile components are therefore protected from high heat, which is used to denature the nucleic acids in the hybridization vessel.

While the '174 patent teaches the use of several chambers in several kinds of diagnostic devices, it does not teach or suggest a first reaction vessel for formation of a hybridization product and a second separate reaction vessel for amplification of a nucleic acid after hybridization has already occurred in the first reaction vessel. Therefore, the '174 patent does not teach or suggest every element of the instant invention. Applicants respectfully request withdrawal of the rejection.

**Rejection of Claims 12, 13 19, 20, and 29 Under 35 U.S.C. §103(a)**

Claims 12, 13, 19, 20 and 29 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over the '174 patent, in view of U.S. Pat. No. 5,695,936 ("the '936 patent"). Applicants respectfully traverse the rejection.

In order to render the invention obvious, the combination of references must teach each and every element of the claims. As discussed above, the '174 patent does not teach or suggest a first reaction vessel for formation of a hybridization product and a second separate reaction vessel for amplification of a nucleic acid after hybridization has already occurred in the first reaction vessel. The '936 patent does not teach or suggest these missing elements. Therefore, the combination of the '174 patent and the '936 patent does not render the instant invention obvious. Applicants respectfully request withdrawal of the rejection.

**Rejection of Claims 17 and 18 Under 35 U.S.C. §103(a)**

Claims 17 and 18 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over the '174 patent, in view of the '936 patent, and in view of Mabilat *et al.* Applicants respectfully traverse the rejection.

In order to render the invention obvious, the combination of references must teach each and every element of the claims. As discussed above, the '174 patent does not teach or suggest a first reaction vessel for formation of a hybridization product and a second separate reaction vessel for amplification of a nucleic acid after hybridization has already occurred in the first reaction vessel. The '936 patent and Mabilat do not teach or suggest these missing elements. Therefore, the combination of the '174 patent, the '936 patent

and Mabilat does not render the instant invention obvious. Applicants respectfully request withdrawal of the rejection.

**Rejection of Claims 26 and 36 Under 35 U.S.C. §103(a)**

Claims 26 and 36 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over the '174 patent, in view of U.S. Pat. No. 5,762,873 ("the '873 patent"). Applicants respectfully traverse the rejection.

In order to render the invention obvious, the combination of references must teach each and every element of the claims. As discussed above, the '174 patent does not teach or suggest a first reaction vessel for formation of a hybridization product and a second separate reaction vessel for amplification of a nucleic acid after hybridization has already occurred in the first reaction vessel. The '873 patent does not teach or suggest these missing elements. Therefore, the combination of the '174 patent and the '873 patent does not render the instant invention obvious. Applicants respectfully request withdrawal of the rejection.

**Rejection of Claim 28 Under 35 U.S.C. §103(a)**

Claim 28 stands rejected under 35 U.S.C. §103(a) as allegedly obvious over the '174 patent, in view of U.S. Pat. No. 5,457,027 ("the '027 patent"). Applicants respectfully traverse the rejection.

In order to render the invention obvious, the combination of references must teach each and every element of the claims. As discussed above, the '174 patent does not teach or suggest a first reaction vessel for formation of a hybridization product and a second separate reaction vessel for amplification of a nucleic acid after hybridization has already occurred in the first reaction vessel. The '027 patent does not teach or suggest these missing elements. Therefore, the combination of the '174 patent and the '027 patent does not render the instant invention obvious. Applicants respectfully request withdrawal of the rejection.

**Rejection of Claims 10, 11-13, 14-16, 17, 19-36 Under the Judicially Created**

**Doctrine of Obviousness-Type Double Patenting**

Claims 10, 11-13, 14-16, 17, 19-26 stand rejected under the judicially-created doctrine of obviousness-type double patenting over U.S. Patent No. 6,300,068 alone or in combination with another document.

While not in agreement with the Office Action on this rejection, Applicants, in the interest of efficient prosecution of this application, herewith agree to submit a terminal disclaimer over U.S. Pat. No.6,300,068 upon indication of allowable claims.

Respectfully submitted,

Date: 11/14/06

By: /Lisa M.W. Hillman/

**Lisa M.W. Hillman, PhD**  
Reg. No. 43,673